

R E M A R K S

Applicant has carefully reviewed the Office Action dated June 23, 2003, regarding the above-referenced patent application. Currently claims 1, 2, 5-8, 15-18, 22 and 24 are pending in the application, wherein claims 1, 2, 5-8, 15-18, 22 and 24 have been rejected. Consideration of the following remarks in view of the current claims is respectfully requested.

Applicant would like to point out that an IDS and associated Form 1449 was filed January 25, 2002. The Examiner has not indicated receipt and consideration of the IDS and has not returned an initialed Form 1449. A copy of the filed IDS and stamped returned postcard confirming receipt by the Patent Office is included with this response. Consideration is requested along with return of an initialed Form 1449 with the next action.

Claims 1, 2, 5-8, 15 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by Yoon et al. (U.S. Patent No. 5,800,394). Applicant respectfully traverses this rejection. Yoon et al. fail to teach a biliary catheter for endoscopic retrograde cholangiopancreatography procedures as claimed in claim 1 of the current application. The device of the current invention facilitates cannulation of the papilla of Vater by enlarging the orifice of the papilla of Vater, thus providing a dilated opening to freely allow passage of subsequent medical devices to pass through the orifice. Yoon et al. fails to teach at least this element of the current invention. Yoon et al. teach a puncturing instrument for creating a space at an obstructed site where normally no space exists. *See Abstract of Yoon et al.* For example, Figures 18 and 19 demonstrate that the Yoon et al. instrument forces adjacent layers of tissue apart in order to create an operation space where otherwise no passage exists. Therefore, the instrument taught in Yoon et al. is an invasive device creating a puncture point at the entry point to the body. However, the biliary catheter as claimed in the current invention is a generally non-invasive device for accessing portions of the biliary

tree through the alimentary canal. For at least these reasons, the Applicant asserts that Yoon et al. fail to teach what is claimed in claim 1. Therefore, claim 1 is in condition for allowance. Claims 2, 5-8, 15 and 16 depend from claim 1 and contain significant additional elements. Therefore, they are also believed in condition for allowance.

Claims 17, 18, 22 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon et al. in view of Karpiel et al. (U.S. Patent No. 5,320,602). Applicant respectfully traverses this rejection. As stated above, Yoon et al. fail to teach what is recited in the pending claims. Namely, Yoon et al. fail to teach a biliary catheter for endoscopic retrograde cholangiopancreatography procedures. Yoon et al. teach an invasive device for creating a space where normally no space exists. Karpiel et al. teach a peel-away catheter for accessing a biliary tree. A guidewire may be inserted within the catheter and the catheter may be removed, leaving the guidewire in place to guide subsequent devices through the alimentary canal. However, Karpiel et al. fail to teach a device for enlarging the orifice at the papilla of Vater as taught in the current application. In view of the teachings of the prior art references, there is no suggestion or motivation to combine the teachings of Yoon et al. with those of Karpiel et al. The devices taught in Yoon et al. and Karpiel et al. are intended to be used for unrelated purposes and function very differently. Therefore, they may be considered nonanalogous art for purposes of reliance in an obviousness rejection. Neither prior art reference addresses the need to enlarge the orifice at the papilla of Vater to facilitate cannulation.

There is no motivation or suggestion for one of ordinary skill in the art to combine the teachings of Yoon et al. with those of Karpiel et al. Therefore, Applicant believes a *prima facie* case of obviousness has not been established and withdrawal of the rejection is respectfully

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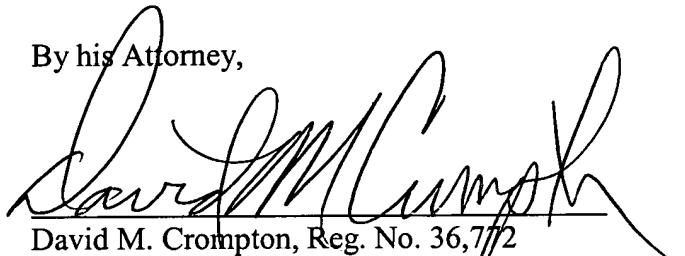
requested. It is believed that claims 17, 18, 22 and 24 each contain patentable subject matter not taught in the prior art of record, placing all claims in condition for allowance.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,



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